IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EAGLE PHARMACEUTICALS, INC., Plaintiff, v. SLAYBACK PHARMA LLC, Defendant.	C.A. No. 18-1953-CFC **PUBLIC VERSION**

REPLY BRIEF IN FURTHER SUPPORT OF SLAYBACK PHARMA LIMITED LIABILITY COMPANY'S MOTION FOR JUDGMENT ON THE PLEADINGS

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I. Introduction

Though Eagle strives mightily in its opposition brief to manufacture an issue of fact to defeat Slayback's motion for judgment on the pleadings, no amount of ink can obscure the fact that Eagle is legally barred by the disclosure-dedication doctrine ("DDD") from asserting that Slayback's bendamustine formulation infringes the patents-in-suit under the DOE. Eagle's reliance on inapposite cases and matters outside the pleadings to support its opposition is a screaming red flag that should alert the Court to the weakness of Eagle's position. No further fact or expert discovery is required to evaluate Slayback's motion, which should be granted for the reasons set forth below and in Slayback's opening brief.

II. Eagle's Reliance on the Federal Circuit's Decision in *Nalco* is Misplaced

Eagle's opposition brief faults Slayback for failing to cite to the Federal Circuit's decision in *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337 (Fed. Cir. 2018), which Eagle erroneously suggests is dispositive of Slayback's motion. (D.I. 20 at 1, 6-8 ("Remarkably, Slayback fails to cite *Nalco*, yet asks the Court to render judgment on the pleadings based on the disclosure-dedication doctrine.")). The short response to Eagle's argument is that *Nalco* has nothing to do with the DDD. In fact, the DDD is not even mentioned in that decision.

The district court in *Nalco* had dismissed plaintiff's complaint for failure to state a claim for direct or indirect infringement. The Federal Circuit reversed because it found that Nalco's motion hinged on the interpretation of certain claim terms that the district court had not yet construed. The Court found that plaintiff's allegation that these terms covered the accused device was "plausible," and that Nalco's competing interpretation of these terms could not be resolved without a *Markman* hearing. *Nalco*, 883 F.3d at 1840-41 ("The 'purpose of a motion to dismiss is to test the sufficiency of the complaint, not to decide the merits.'"). Therefore, it reversed and remanded the case for further proceedings.

Importantly, *Nalco* did *not* hold that all "questions over the proper interpretation of a patent's intrinsic record are 'not suitable' and 'particularly inappropriate' for resolution on a motion to dismiss," as Eagle contends. In fact, Judge Stark rejected this very argument in granting a post-*Nalco* motion to dismiss based on the doctrine of prosecution history estoppel. *See Amgen Inc. v. Coherus Biosciences, Inc.,* No. 17-546-LPS-CJB, 2018 U.S. Dist. LEXIS 56320, at *11 n.5 (D. Del. Mar. 28, 2018). Addressing the plaintiff's reliance on *Nalco*, Judge Stark explained: "In Nalco the parties had disputes over the proper construction of claim terms that were inappropriate to resolve on a motion to dismiss. Here no such disputes have been identified – only a legal dispute that, in the Court's view, turns on the clear and unambiguous prosecution history." *Id.*

Judge Stark's comments are equally applicable here. No claim construction dispute has been identified by Eagle concerning the claim limitations at issue, nor does one exist. Moreover, the DDD, like prosecution history estoppel, is a question of law, which can be resolved on a motion for judgment on the pleadings. *See, e.g., In re Bendamustine Consol. Cases*, No. 13-2046-GMS, 2015 U.S. Dist. LEXIS 55963 (D. Del. Apr. 29, 2015).

III. Eagle's Reliance on Dr. Amiji's Declaration Is Improper

Although Eagle admits that "matters outside the pleadings may not be considered" in the context of a motion for judgment on the pleadings (D.I. 20 at 11), it nonetheless invites the Court to rely on an expert declaration from Dr. Amiji, which purportedly raises a factual question concerning a POSA's understanding of the disclosures in the specification of the patents-in-suit. The Court should reject Eagle's invitation to commit error. Indeed, the law could not be clearer that expert declarations may *not* be considered in deciding a motion for judgment on the pleadings. *See, e.g., Intellectual Ventures I LLC v. T-Mobile USA, Inc.*, No. 13-1632-LPS, 2017 U.S. Dist. LEXIS 134551, at *18-19 (D. Del. Aug. 23, 2017) (citing, among others, *Mele v. FRB*, 359 F.3d 251, 257 (3d Cir. 2004) for the proposition that "[i]n deciding a Rule 12(c) motion, the court does

not consider matters outside the pleadings.").

In any event, Dr. Amiji's declaration, like Eagle's argument, misperceives the standard for the DDD, which "bars a patentee from using the doctrine of equivalents to recapture claim scope that it disclosed in the specification but did not literally include in the patent's claims." *See CSP Techs., Inc. v. Sud-Chemie AG*, 643 F. App'x 953, 958 (Fed. Cir. 2016). In determining whether the DDD applies, the sole question is whether "one of ordinary skill in the art could identify which subject matter has been disclosed and which subject matter has been claimed." *Aventis Pharms., Inc. v. Barr Labs., Inc.*, 335 F. Supp. 2d 558, 577-78 (D.N.J. 2004). Expert testimony is not required to answer this question where, as here, the language of the patent is clear on its face and there is no allegation that it contains any specialized terms of art. *See In re Bendamustine*, 2015 U.S. Dist. LEXIS 55963, at *11 ("[T]he specification identifies *precise alternatives* to TBA. Thus, it is unnecessary to inquire into whether 'one of ordinary skill in the art could identify the subject matter that had been disclosed [but] not claimed'—the list is self-explanatory."); *Intellectual Ventures I LLC v. Erie Indem. Co.*, 200 F. Supp. 3d 565, 573-74 (W.D. Pa. 2016) (declining to hear expert testimony or construe the claims prior to deciding a motion to dismiss).

Eagle cites *Par Pharmaceuticals, Inc. v. Hospira, Inc.*, No. 17-944-JFB-SRF, 2018 U.S. Dist. LEXIS 114588 (D. Del. Apr. 27, 2018) for the proposition that the Court needs expert testimony to determine how a POSA would interpret the disclosures in the specification in this case. (D.I. 20 at 11-12). But *Par* does not support Eagle's argument. In *Par*, the Court found that it could not consider the defendant's ANDA in deciding defendant's motion to dismiss because it was not attached, or integral, to the pleadings; rather, it was merely summarized in the complaint. The Court therefore distinguished *In re Bendamustine*, in which Judge Sleet granted a motion for judgment on the pleadings without expert testimony after considering portions of the defendant's

ANDA that were integral to the pleadings. *See In re Bendamustine*, 2015 U.S. Dist. LEXIS 55963*; see also Amgen,* 2018 U.S. Dist. LEXIS 56320, at *3-4 (considering the defendant's aBLA on a motion to dismiss). Here, as in *In re Bendamustine*, the relevant portion of Slayback's formulation is attached to the pleadings and is the entire basis for Eagle's allegations of infringement.[1] Accordingly, *Par* is not on point.

IV. Eagle's Argument that the Patents-in-Suit do not Disclose Slayback's Specific Formulation is Irrelevant

A. The DDD Applies To Claim Limitations, Not an Entire Embodiment

Eagle's opposition acknowledges that "[i]n order to find disclosure-dedication, the Court must determine that a POSA would understand that the unclaimed element was identified as an 'alternative' to the claim ***limitation***." (D.I. 20 at 12[2]). Eagle, however, ignores this standard in arguing that the DDD does not apply.

[redacted] In other words, Eagle argues that Slayback's exact formulation must be disclosed in the specification in

[1] Eagle's argument that the portion of Slayback's NDA cited in Slayback's motion is not "integral" to the pleadings is nonsensical. There is no dispute that the relevant portion of Slayback's NDA is attached to Slayback's Answer and Counterclaims. (D.I. 8, Ex. A). This document is explicitly relied upon by Slayback in its counterclaims. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997).

[2] All emphasis in this document is added unless otherwise noted.

order for the DDD to apply. [redacted] Thus, Eagle's argument conflicts with Eagle's own articulation of the DDD standard, which correctly states that the DDD applies "when a POSA would understand that the unclaimed element was identified as an 'alternative' to ***the claim limitation***." (D.I. 20 at 12). Eagle's argument also conflicts with the relevant case law. *See Reckitt Benckiser Pharms. Inc. v. Dr. Reddy's Labs. S.A.*, No. 14-1451-RGA, 2017 U.S. Dist. LEXIS 140633 (D. Del. Aug. 31, 2017); *Aventis*, 335 F. Supp. 2d 558.

In *Aventis*, the patents claimed pharmaceutical compositions consisting of a piperidinoalkanol compound and three specific inert excipients. Several of the accused generic products lacked these three specific inert excipients, but contained other ingredients that the specification identified as "ingredients that may be present in the pharmaceutical composition in an amount up to 95 % by weight." *Aventis,* 335 F. Supp. 2d at 575-76. Defendants moved for summary judgment that the DDD precluded plaintiffs from relying on the DOE to prove infringement. Plaintiffs opposed, arguing that the DDD did not apply because the specification did "not disclose the accused products in their entirety as a discrete embodiment," and did not disclose "Defendants' accused products' specific formulation." *Id*. at 575-76. The court rejected this argument, explaining, "Plaintiffs' argument fails because ***the dedication doctrine encompasses unclaimed subject matter, which includes not only unclaimed embodiments, but also unclaimed elements and limitations***." *Id.* at 577-78.

Similarly, in *Reckitt Benckiser*, the patents claimed a water-soluble film product comprising a "water-soluble polymer component consisting of polyethylene oxide ["PEO"] in

combination with a hydrophilic cellulosic polymer ["HCP"]." 2017 U.S. Dist. LEXIS 140633, at *3-4. The claims further required that the PEO component include certain amounts of low and high molecular weight PEOs. Polyvinyl pyrrolidone ("PVP") was identified in the specification as an alternative to HCP in a list of "Film-Forming Polymers," but was not included in the claims. *Id.* at *7. The plaintiffs argued that defendant's ANDA product, which contained PVP, infringed the claims under the DOE. Plaintiffs contended that the DDD rule did not apply "because there is no passage or example in the '150 patent specification that specifically discloses a combination of low and high molecular weight PEOs with PVP . . . ." *Id.* at *10. The court easily rejected this argument, finding that "[i]t would be clear to a POSA reading the patent as a whole that PVP is disclosed as an alternative to the HCP element of the asserted claims." *Id.* at *11.

Eagle's opposition brief ignores these cases, arguing that the Federal Circuit "dealt with a similar issue" in *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 429 F.3d 1364, 1379 (Fed. Cir. 2005) that "did not look at the limitation of saccharides in isolation." (D.I. 20 at 16). But Eagle misrepresents *Pfizer,* which involved a claim limitation that required "a suitable amount of a saccharide to inhibit hydrolysis." *Pfizer,* 429 F.3d at 1379. In *Pfizer,* the defendants argued that their ANDA products, which contained microcrystalline cellulose ("MCC"), could not infringe the saccharide limitation under the DOE because the patentee had dedicated MCC to the public. The court rejected this argument because "Ranbaxy has not pointed to parts of the '450 patent where the inventors identify microcrystalline cellulose as an unclaimed alternative that would function as a 'saccharide' to inhibit hydrolysis." *Id*. In so ruling, the court acknowledged that "Ranbaxy is correct to the extent that it points out that our precedent addressing the disclosure-dedication rule appears to deal only with patents in which subject matter is disclosed *as an alternative to the relevant claim limitation*." *Id.* at 1378. Thus, *Pfizer* actually supports Slayback's position that the

DDD is triggered by the specification's identification [redacted]

B. Eagle's Argument that the Patents-in-Suit Teach Away from Using [redacted] Is Irrelevant

Eagle, through reliance on the improperly submitted Amiji Declaration, also argues that the DDD does not apply because a POSA would understand the patents-in-suit [redacted] This argument is a complete red herring and should not be given any weight.

[redacted]

More importantly, to invoke the DDD, it does not matter whether the disclosed alternative embodiment would work as well as, or in the same way as, the claimed formulation. All that is required is that a POSA would recognize the disclosure as an alternative to the relevant claim limitation, *i.e.*, [redacted] *See The Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1334 (Fed. Cir. 2004) ("[T]he disclosure-dedication rule does not impose a § 112 requirement on the disclosed but unclaimed subject matter. The standards articulated in § 112 are directed to the *claimed* invention, not to disclosures in the written description that may implicate the disclosure-dedication rule."). [redacted]

[redacted]

[redacted]

V. Eagle's Reliance on *Graver Tank* is Misplaced

Eagle also argues that application of the DDD is contrary to the Supreme Court's 1950 decision in *Graver Tank & Manufacturing Co. v. Linde Air Products Co.,* 339 U.S. 605 (1950) ("*Graver II*"). (*See* D.I. 20 at 18-20). But the Federal Circuit explicitly distinguished *Graver II* in *Johnson & Johnston Associates v. R.E. Service Co., Inc.,* 285 F.3d 1046, 1053 (Fed. Cir. 2002), a case that Eagle mentions but never substantively addresses. In *Johnson & Johnston,* the patent claimed an aluminum substrate, but the specification disclosed that "other metals, such as stainless steel or nickel alloys may be used." *Id.* at 1055. The *en banc* Federal Circuit held that the DDD precluded the patentee from relying on the DOE to extend its claim to cover a steel substrate. In so ruling, the Federal Circuit explained that its holding was not in conflict with *Graver II. Id.* at 1054 n.l.

The Federal Circuit first observed that the patent in *Graver II* initially issued with broad claims that covered the alleged equivalent, but these claims were later invalidated. *Id.* at 1053. Because the PTO had had the opportunity to examine these broader claims, the Court found that the patentee's reliance on the DOE in *Graver II* did not implicate the policy concerns underlying the DDD. *Id.* The Court therefore concluded that *Graver II* did not abrogate the DDD.

VI. Eagle's Other Arguments Are Easily Rejected

Eagle also argues that it should be given leave to amend its complaint "[i]f the Court finds the Complaint defective." (D.I. 20 at 3 n.2). However, no amendment can cure the problem with Eagle's infringement allegation under the DOE, which arises as a matter of law from the disclosure made in the specification of the patents-in-suit. Accordingly, amendment of the complaint would

be futile. *Amgen*, 2018 U.S. Dist. LEXIS 56320, at *10 ("Given the Court's conclusions about the clear and unmistakable disclaimer in the prosecution history, necessitating dismissal of Amgen's claim for infringement under the doctrine of equivalents, and given Amgen's acknowledgement that Coherus does not literally infringe, amendment of the complaint would be futile.").

Eagle also argues that that it "should be allowed discovery to conduct a full infringement analysis, including product samples and development documents, as well as having its experts access Slayback's NDA." (D.I. 20 at 10). But as Slayback explained in its opening brief, Eagle received samples of Slayback's proposed 505(b)(2) product as well Slayback's entire 505(b)(2) application in the fall of 2018. (D.I. 15 at 4 n.5, Ex. C). Slayback notified Eagle in November 2018 that its expert could test these samples and review Slayback's NDA. (*Id.*). Nevertheless, Eagle offers no evidence or reason to believe that Slayback's product contains any ingredients besides those identified in Slayback's 505(b)(2) application. Accordingly, no amount of discovery will affect the DDD issue before the Court.

VII. Conclusion

For the foregoing reasons, as well as those set forth in Slayback's opening brief, Slayback respectfully urges the Court to grant its motion for judgment on the pleadings.

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